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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/483,382	06/07/95	THOMPSON R	04189.3083-0

1802/0606

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EXAMINER	
KAUFMAN, C	
ART UNIT	**PAPER NUMBER**
1812	11

DATE MAILED: 06/06/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1-30-97.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) ____ is/are withdrawn from consideration.

☐ Claim(s) ____ is/are allowed.

☐ Claim(s) ____ is/are rejected.

☐ Claim(s) ____ is/are objected to.

☒ Claims 1-36 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on ____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on ____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) ____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: ____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice to Comply

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). ____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

★ U.S. GPO: 1996-410-238/40050

DETAILED ACTION

Sequences

1. The current application contains sequences that were not present in a parent application prior to October 1, 1990. These sequences are shown in Figures 31, 32, 33, 40, 55, 56, 57, 58, and a figure with no number but which was submitted with the application (see attached figure). Because these sequences were filed after 10/1/90, they must comply with the requirements set out below.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleic and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth in the attached Notice to Comply with Requirements for Patent Applications Containing Nucleic Sequence and/or Amino Acid Sequence Disclosures. Note that even if a polynucleotide sequence and the encoded polypeptide sequence appear on the same figure, a different sequence identifier must be assigned to each polypeptide and each polynucleotide sequence and be listed individually in the Sequence Listing and CRF.

3. When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and a sequence identifier ("SEQ ID NO:X") must be used either in the drawing or in the Brief Description of the Drawings. See MPEP § 2422.02. In the instant application, a sequence identifier must be used for each sequence appearing in the above listed figures.

Appropriate correction is required.

Election/Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method of treating a medical condition with compound R1-X-R2, classified in class 514, subclass 772.1.

II. Claims 2-4 and 7-13, drawn to a method of treating tumor necrosis factor (TNF) mediated diseases with a TNF inhibitor, a TNF inhibitor, and a TNF inhibitor in a pharmaceutically acceptable carrier, and a kit for the preparation of a TNF inhibitor, classified in class 514, subclass 2.

III. Claims 5-6 and 14-16, drawn to DNA encoding a TNF inhibitor, classified in class 536, subclass 23.1.

IV. Claims 17-21, drawn to an IL-1 inhibitor and kit containing an IL-1 inhibitor, classified in class 530, subclass 350.

V. Claims 22-25, drawn to DNA encoding an IL-1 inhibitor, host cell, and process of preparing the IL-1 inhibitor, classified in class 435, subclass 69.1.

VI. Claims 26-36, drawn to a polymer and polymer compositions, classified in class 424, subclass 78.08.

5. The inventions are distinct, each from the other because of the following reasons:

The method of Invention I is distinct from the methods of Invention II because the compounds used for treatment are distinct because the compound used in Invention I comprises a non-peptidic polymeric group. Additionally, the search required for Invention I requires consideration of the structure (*e.g.*, length, charge, composition) of the non-peptidic polymer group as well as the characteristics of each of the two R compounds and their interaction with each other. Such considerations are not required for Invention II, which instead requires consideration of TNF function and specific diseases mediated by TNF.

The method Invention I is unrelated to the products of Inventions III-VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions recite distinct

products. The method of Invention I uses a product which is structurally different from the products of the other inventions, being made of two potentially different biologically active polypeptidic compounds with an intervening non-peptidic polymeric group. The distinct structure implies a different function and mode of operation. Additionally, the method of Invention II requires unique considerations not required for the products of Inventions III-VI, such as the mode of administration, dosage, and the particular diseases to be treated.

The inhibitor of Invention II is structurally and functionally different from the DNA of Invention III. Additionally, the inhibitor can be made by a materially distinct method not requiring the DNA encoding it, such as chemical synthesis. In the instant case the DNA of Invention III cannot be used in or produced by the method of Invention II.

Inventions II and Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Invention II requires a TNF inhibitor to be used for treatment and this inhibitor is structurally distinct from the products of Inventions IV-VI, which would not reasonably be expected to be functional equivalents of the TNF inhibitor. Additionally the search required for the method of Invention II involves unique considerations such as mode of administration, dosage, and the particular diseases to be treated. In the instant case the TNF-inhibitor of Invention II is structurally distinct from the polypeptide, DNA, and polymer of Inventions IV-VI, respectively. Even though Invention VI may contain a TNF-inhibitor, one skilled in the art would reasonable expect that attachment of a polymer to the inhibitor would effect its function. Additionally, polymer containing compounds require different search considerations such as length and type of polymer.

Inventions III and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01).

In the instant case the DNA of Invention III is structurally and functionally distinct from the polypeptide, DNA, and polymer of Inventions IV-VI, respectively.

The polypeptide of Invention IV is structurally and functionally different from the DNA of Invention V. Additionally, the protein can be made by a materially distinct method not requiring the DNA encoding it, such as chemical synthesis.

Inventions IV and V, which are themselves distinct, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the IL-1 inhibitor and DNA encoding it are structurally and, presumable, functionally distinct from the polymer and polymer compositions of Invention VI.

6. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, and the search required for one Invention is not coextensive with the search required for any other Invention, restriction for examination purposes as indicated is proper.

7. Claims 2, 4, 7, and 11-13 of Invention II are generic to a plurality of disclosed patentably distinct species comprising a polypeptide encoded by the polynucleotide sequences shown in Figures 32, 39, 40, 56, or 58, or having the amino acid sequences shown in Figures 38, 56, and 57 (note that the specie with the sequence shown in Figure 56 is considered to be a single specie whether claimed by the DNA shown in Fig. 56 or the DNA encoding the amino acid sequence shown in Fig. 56) ; and claims 14-16 of Invention III are generic to a plurality of disclosed patentably distinct species comprising a DNA having the polynucleotide sequences shown in Figures 32, 39, 40, 56, or 58, or encoding the amino acid sequences shown in Figures 38, 56, and 57 (note that the specie with the sequence shown in Figure 56 is considered to be a single specie whether claimed by the DNA shown in Fig. 56 or the DNA encoding the amino acid sequence shown in Fig. 56). If Invention II or Invention III is elected, an election of a single species as set

forth above must be included. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. A telephone call was made to M. Paul Barker on 5/30/97 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached at (703) 308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

The Art Unit 1812 Fax Center number is (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

cmk
June 3, 1997

Stephen Walsh
STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800